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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,110	SIEGEL ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/6/08, 8/1/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,27-29 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,27-29,37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 6 June 2008 and 1 August 2008 have been entered. Claims 1 - 17, 27 – 29, and 37 are pending and under examination.

Withdrawn Rejections and Objections

2. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection under 35 USC 112, first paragraph, for lack of adequate written description (rejection number 3 in the office action mailed 10 March 2008) is withdrawn in light of the amendments to the claims. The claims no longer encompass administration of agonists, which had not been considered described.

B. The rejection under 35 USC 112, second paragraph is withdrawn in light of the amendments which clarify the scope of patent protection sought.

C. The rejection of claims 1, 14 – 17, and 27 – 28 under 35 USC 102(b) as anticipated by Kiyashchenko is withdrawn in light of the amendments. The claims now require administration to an individual who is overweight, suffers from a weight disorder, or suffers from obesity, which is not taught by the reference. Note however the rejection of newly-added claim 37 as anticipated by Kiyashchenko.

D. The rejection of claims 1, 14 – 17, and 27 – 28 under 35 USC 102(b) as anticipated by Haynes is withdrawn in light of the amendments. The claims now require administration to an individual who is overweight, suffers from a weight disorder, or suffers from obesity, which is not taught by the reference. Note however the rejection of newly-added claim 37 as anticipated by Haynes.

E. The rejection of claims 1, 6, 14 – 17, and 27 – 28 under 35 USC 102(e) as anticipated by Siegel (U.S. Patent 7,112,566) is withdrawn in light of the amendments. The claims now require administration to an individual who is overweight, suffers from a weight disorder, or suffers from obesity, which is not taught by the reference. Note however the rejection of newly-added claim 37 as anticipated by Siegel.

F. The rejection of claims 1, 6, 14 – 17, and 27 – 28 under 35 USC 102(e) as anticipated by Siegel (U.S. Patent 7,335,640) is withdrawn in light of the amendments. The claims now require administration to an individual who is overweight, suffers from a weight

disorder, or suffers from obesity, which is not taught by the reference. Note however the rejection of newly-added claim 37 as anticipated by Siegel.

G. The rejection under 35 USC 102(b) as anticipated by Taheri is withdrawn in light of the amendments. The claims now require administration to an individual who is overweight, suffers from a weight disorder, or suffers from obesity, which is not taught by the reference. Note however the rejection of newly-added claim 37 as anticipated by Taheri.

H. The double-patenting rejections of claims 1, 14 – 15, 17, and 27 – 28 over U.S. Patents 7,112,566 and 7,335,640 and the provisional rejection over application 11/937891 are withdrawn. The claims now require administration to an individual who is overweight, suffers from a weight disorder, or suffers from obesity, which is not recited in the claims of either patent. Note however the rejection of newly-added claim 37 for double-patenting over these two patents and the application.

Maintained Rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 16 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of hypocretin-1 or hypcretin-2, does not reasonably provide enablement for preventing or treating excess body weight as recited in claims and 37. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

This rejection is maintained for the reasons of record. The reasons why the claims are not enabled over their full scope are set forth in the previous office action and for the sake of brevity will not be repeated in their entirety here. Briefly, claim 1 is drawn to treating and preventing excess body weight; claim 37 encompasses treating excess body weight in a subject who either is overweight or who may become overweight in the future. That is, both claims encompass treatment of excess body weight and prevention of same. The specification fails to show reduction to practice of either treatment or prevention of body weight. The art of record indicates that administration of hypocretins increases food intake. See for example Haynes and Preti, both previously made of record, which indicate that administration of hypocretins increases food intake by up to 10-fold. Increasing food intake 10-fold would be expected to result in increase in body weight, and certainly would not be expected to prevent or treat excessive body weight. Additionally, Preti teaches that a hypocretin antagonist decreases feeding, further supporting the notion that hypocretin itself will not result in weight loss or prevention of weight gain.

Applicant argues that the specification need not show an actual working example or reduction to practice in order for it to be enabled. Of course this is true in the abstract, but in this case, what is claimed is in direct opposition to what is known in the art. The claims are drawn to keeping weight gain from occurring, or to treating excessive weight, by administering products well-known in the art to increase feeding. The specification fails to show actual reduction to practice commensurate in scope with the claims, and fails to provide guidance to the skilled artisan as to how to overcome the art-recognized obstacles to weight loss and prevention of weight gain following administration of hypocretins. Given the breadth of the claims, the lack of working examples, and the state of the prior art which in fact contradicts what is claimed, and the lack of lack of guidance as to how to reverse the effects of the drugs to be administered, it would take undue experimentation for the skilled artisan to practice the method commensurate in scope with the claims, particularly as the artisan must administer “an effective dosage regime” as recited in claims 1 and 37. The specification fails to show what such an effective dosage regime is, and offers no guidance as to how to go about determining what such a regime is. Therefore, the rejection stands.

Rejections and Objection Necessitated by Amendment

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Kiyashchenko 2001 (Journal of Neurophysiology 85:2008 – 2016, of record).

Claim 37 is broad in that it encompasses administration of certain products to individuals who either have excess body weight or are "at risk of developing excess body weight". The claim therefore reads on administration to any and all individuals, since all individuals have some degree of risk of developing excess body weight. Kiyashchenko teaches administration of orexin-A and orexin-B (which are synonyms of hypocretin-1 and -2 respectively; see specification paragraph [46]) at p. 2009 first column. The animals show inactivity, as they are rats which are inactive during the daytime. Thus they have one of the behavioral symptoms recited in claim 37. As the reference teaches administering the same products to the same patient populations recited in the claim, the claim is anticipated.

5. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Haynes 1999 (Peptides 20:1099 – 1105, of record).

Claim 37 is broad in that it encompasses administration of certain products to individuals who either have excess body weight or are "at risk of developing excess body weight". The claim therefore reads on administration to any and all individuals, since all individuals have some degree of risk of developing excess body weight. Haynes teaches administration of orexin-A and orexin-B (which are synonyms of hypocretin-1 and -2 respectively; see

specification paragraph [46]) at p. 1100 second column. The animals show inactivity, as they are rats which are inactive during the daytime. Thus they have one of the behavioral symptoms recited in claim 37. As the reference teaches administering the same products to the same patient populations recited in the claim, the claim is anticipated. Additionally, Haynes teaches constant infusion of orexins for 8 days. As administration causes an increase in food intake (Haynes, Figure 1), the 8-day infusion includes administration to animals that are overeating as recited in claim 37.

6. Claim 37 is rejected under 35 U.S.C. 102(e) as being anticipated by Siegel (U.S. Patent 7,112,566).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 37 is broad in that it encompasses administration of certain products to individuals who either have excess body weight or are "at risk of developing excess body weight". The claim therefore reads on administration to any and all individuals, since all individuals have some degree of risk of developing excess body weight. Siegel teaches administration of hypocretin to subjects; see for example claims 1 and 6 of the patent. Siegel teaches and claims treatment narcolepsy, which is characterized by attacks of sleep and motionlessness. Therefore the patients who receive the drug are at risk of weight gain and show a behavioral symptom of a weight disorder, namely inactivity. As the reference teaches administering the same products to the same patient populations recited in the claim, the claim is anticipated.

7. Claim 37 is rejected under 35 U.S.C. 102(e) as being anticipated by Siegel (U.S. Patent 7,335,640).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 37 is broad in that it encompasses administration of certain products to individuals who either have excess body weight or are "at risk of developing excess body weight". The claim therefore reads on administration to any and all individuals, since all individuals have some degree of risk of developing excess body weight. Siegel teaches administration of hypocretin-1 to subjects; see for example claims 1 and 8 of the patent. Siegel teaches and claims treatment narcolepsy, which is characterized by attacks of sleep and motionlessness. Therefore the patients who receive the drug are at risk of weight gain and show a behavioral symptom of a weight disorder, namely inactivity. As the reference teaches administering the same products to the same patient populations recited in the claim, the claim is anticipated.

8. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Taheri 2001 Spring Meeting, Royal College of Physicians, London (of record).

Claim 37 is broad in that it encompasses administration of certain products to individuals who either have excess body weight or are "at risk of developing excess body weight". The claim therefore reads on administration to any and all individuals, since all individuals have some degree of risk of developing excess body weight. Taheri teaches administration of orexin-A (which is a synonym of hypocretin-1; see specification paragraph [46]). The animals show inactivity, as they are rats which are inactive during the daytime, note "animals spent more time being still in the subsequent 20 hours" after the first four-hour period following injection. Thus they have one of the behavioral symptoms recited in claim 37. As the reference teaches administering the same products to the same patient populations recited in the claim, the claim is anticipated.

9. Claims 17 and 27 - 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Stricker-Krongrad 2002 (Regulatory Peptides 104:11-20, note that the face page of the attached reference indicates it was available online on 11 December 2001).

Stricker-Krongrad teaches administration of hypocretin-1 and hypocretin-2 to obese mice. See p. 12 first complete paragraph for identification of obese mice and p. 14 section 2.4.2 for explanation of administration of the peptides. At p. 16 Figure 6, the reference indicates that administration of both hypocretin-1 and hypocretin-2 are effective in raising a metabolic rate, as

required by claims 27 – 28. Note that metabolic rate was monitored (see Figure 6 lower panel), as recited in claim 29. Although the reference is silent as to whether or not a motor or muscular activity is increased following administration, this is an effect that is inherent upon administration of dosage. Absent evidence to the contrary, it is presumed that the dosage regime administered is effective for increasing a motor or muscular activity. Note that feeding activity, which requires mouth and intestinal muscles to be used, increases upon administration of the peptides to obese mice (see Figure 5).

Claims 1 – 16 and 37 are not included in this rejection as these claims explicitly require administration of an effective dosage of hypocretin-1 or hypocretin-2 for treatment or prevention of weight gain. The reference by Stricker-Krongrad indicates that administration of hypocretins (orexins) does not decrease body weight or attenuate weight gain, in fact it increases food intake, so the dosage administered is not effective for decreasing weight or preventing weight gain as required by the claims.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 37 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 16 of U.S. Patent No. 7,112,566. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case the claims encompass administration of hypocretin to subjects including for prophylaxis, or without any particular disease or condition listed, whereas in the '566 patent the claims are more specific in that they are drawn to administration to specific patient populations. Note that the narcoleptic individuals treated in the claims of the '566 patent have inactivity as recited in instant claim 37, due to their narcolepsy.

11. Claim 37 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 18 of U.S. Patent No. 7,335,640. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case the claims encompass administration of hypocretin to subjects including for prophylaxis, or without any particular disease or condition listed, whereas in the '640 patent the claims are more specific in that they are drawn to administration to specific patient populations. Note that the narcoleptic individuals treated in the claims of the '640 patent have inactivity as recited in instant claim 37, due to their narcolepsy.

12. Claim 37 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 18 of copending Application No. 11/937891. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case the claims encompass administration of hypocretin-1 to subjects including for prophylaxis, or without any particular disease or condition listed, whereas in the '891 application the claims are more specific in that they are drawn to administration to specific patient populations. Note that the narcoleptic individuals treated in the claims of the '891 application have inactivity as recited in instant claim 37, due to their narcolepsy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Inventorship

13. Claim 37 is directed to an invention not patentably distinct from claims of commonly assigned U.S. Patents 7,112,566 and 7,335,640 and application 11/937891 as set forth in the double-patenting rejections above.

14. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 7,112,566 and 7,335,640 and application 11/937891, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Note no assignment was filed in this case upon entry to the national stage. Thus there is not evidence that the inventions were commonly owned at the time of invention of the subject matter claimed in this case.

15. It is noted that a new application data sheet was filed on 1 August 2008. The sole changes in this application data sheet are to the name and address of the second inventor. The change of name has not been entered. See MPEP § 605.04(b), which states in part that:

> Except for correction of a typographical or transliteration error in the spelling of an inventor's name, a request to have the name changed from the typewritten version to the signed version or any other corrections in the name of the inventor(s) will not be entertained, unless accompanied by a petition under 37 CFR 1.182 together with an appropriate petition fee. >Since amendments are not permitted after the payment of the issue fee (37 CFR 1.312), a petition under 37 CFR 1.182 to change the name of the inventor cannot be granted if filed after the payment of the issue fee.< The petition should be directed to the attention of the Office of Petitions.

Since neither a petition nor fee was received, the name change has not been entered.

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./
Patent Examiner, Art Unit 1649
August 22, 2008